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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/938,801 | 08/24/2001 | J. Bryan Jones | GC525-2D1 | 3593 |

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/938,801 | Applicant(s) JONES ET AL. | |
| | Examiner Richard G Hutson | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 and 24-33 are at issue and are present for examination.

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-13 in Paper No. 4 is acknowledged.

Claims 24-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Applicants amendment of the first line of the specification to state that this application is a divisional of application 09/234,956, filed January 21, 1999, is acknowledged. It is further noted that this application claims the benefit of U.S. Provisional Patent Application Serial No. 60/072,266, filed January 23, 1998, which is incorporated by reference.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the

list may not be incorporated into the specification but must be submitted in a separate paper."

Claim Objections

Claims 1 and 5 are objected to because of the following informalities:

Claim 1 recites "...replacing thiol hydrogen in the cysteine residues with a thiol side chain". It is suggested that this be amended to " replacing the thiol hydrogen in the cysteine residue[s] with a thiol side chain".

Claim 5 recites "...replacing thiol hydrogen in at least some of the cysteine residues with a thiol side chain". It is suggested that this be amended to " replacing the thiol hydrogen in at least some of the cysteine residues with a thiol side chain".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (2-13 dependent on) is indefinite in that it is confusing in the recitation "... providing a chemically modified mutant enzyme with one or more amino acid residues from an enzyme being replaced by cysteine residues, wherein at least some of

the cysteine residues are modified by replacing thiol hydrogen in the cysteine residues with a thiol side chain". As the claimed invention is a method, this recitation is unclear to the extent that by "providing a chemically modified mutant enzyme" it is unclear if the act of chemically modifying a mutant enzyme is a part of the claimed method or is the method merely directed at assaying a chemically modified mutant enzyme, that was previously prepared. In the interest of advancing prosecution the claim has been interpreted as broadly as reasonably possible, which is such that the claimed method is directed to a method of assaying a "chemically modified mutant enzyme" which was not necessarily modified as a part of the claimed method, but merely provided as a part of the claimed method, which is interpreted as the method steps are directed to this provided chemically modified mutant enzyme". As such this portion of the claim is further interpreted as a product by process type of recitation, and the only portion of the recitation that has patentable weight are the limitations of the chemically modified mutant enzyme itself, not the process by which it was made. Thus the claim is interpreted as a method for screening chemically modified mutant enzymes for amidase and/or esterase activity comprising : providing a chemically modified mutant enzyme, wherein said chemically modified mutant enzyme has at least some cysteine residues that have been modified by replacing the thiol hydrogen with a thiol side chain, contacting the chemically modified mutant enzyme with a substrate for an amidase and/or a substrate for an esterase; and determining whether the chemically modified mutant enzyme exhibits amidase and/or esterase activity.

Claim 4 is indefinite for the same reason discussed above for claim 1, with respect to "providing cysteine mutants of an enzyme". As such claim 4 does further limit claim 1, such that it adds the additional step of "...combining the cysteine mutants of an enzyme, the methanethiosulfonate reagents and buffer...", but it remains unclear if the claimed method comprises the actual cysteine modification of a enzyme.

Claim 10 is indefinite in that given the above indefiniteness and interpretation of claim 1, claim 10 does not further limit claim 1.

Claims 11 and 12 are indefinite in that the recitation "subsite" is unclear. It is acknowledged that on page 7, lines 23-29, of the specification applicants briefly discuss subsites and give a reference for further discussion, however, this brief discussion is insufficient to clearly define applicants intent in the recitation "subsite".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Mutus et al. (Biochem. Biophys. Res. Comm., Vol. 112, NO. 3, 941-947, 1983).

Mutus et al. teach the modification of acetylcholinesterase with the fluorescent thiol reagent S-mercuric-N-dansylcysteine and the measurement of the esterase activity

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of this modified mutant enzyme (See above 112 2nd paragraph rejection). Thus, Mutus et al. anticipates claims 1, 3, 4 and 10.

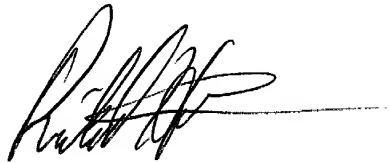
Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
February 24, 2003